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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,729	11/13/2001	Moses Rodriguez	1199-1-005CIP2	4304

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/010,729	RODRIGUEZ ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/15/06, 11/20/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42,43,73 and 91-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *73* is/are allowed.

6)☒ Claim(s) *42-43,91-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 September 2006 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 42 – 43, 73, and 91 – 93 are pending and under examination.

Withdrawn Rejections and Objections

4. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejection of claims 42, 73, and 91 – 93 under 35 USC § 112, first paragraph for lack of enablement commensurate in scope with the claims is withdrawn in light of the amendments. The amendments require that the antibodies, or specific antigen-binding fragments thereof, bind to oligodendrocytes and induce remyelination. Note however the rejection of claims 42 – 43 for lack of enablement due to lack of biological deposit is maintained (see below).

B. The rejection of claims 42 and 91 under 35 USC § 112, first paragraph for lack of adequate written description is withdrawn in light of amendments. The claims no longer read on broad genera beyond what is actually described in the specification.

Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

5. Claims 42 – 43, and 91 – 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims recite the limitation "a .. sequence of". For example, claim 42 recites "a heavy chain variable region sequence of SEQ ID NO:7 and ... a light chain variable sequence of

SEQ ID NO:9". Claim 91 recites "an amino acid sequence set out in Figure 35" and "an amino acid sequence set out in Figure 36".

It is unclear whether the claims read on the full-length sequence of SEQ ID NO:7 and 9, or whether the scope of the claims is broader than that. The broadest reasonable interpretation of terms such as "an amino acid sequence set out in Figure 35" includes any sequence; i.e. a subsequence of the full-length sequence. In contrast, claim 73 is not indefinite as it recites "comprising the amino acid sequence set out in Figure 35". Amending the claims to recite "comprising the heavy chain variable region sequence of SEQ ID NO:7", for example, would be sufficient to obviate this rejection.

Maintained Rejections

Priority

6. Applicant is reminded that the effective filing date for all pending claims is 28 May 1999. The newly-added recitation of antibody fragments in claims 42 and 91 finds support in application 09/322862 (filed 28 May 1999) at page 40 lines 2 – 5 for example.

Claim Rejections - 35 USC § 112

7. Claims 42 – 43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for the reasons of record with respect to the deposit of the monoclonal antibody sHIgM22 (LYM 22). The specification provides guidance as to how to make and use antibodies comprising SEQ ID NO:7 and 9, which are contained within LYM 22. Applicant argues that deposit of the monoclonal antibody is not required as specific heavy and/or light chain sequences must be presented, and that it is within the skill of the artisan to make these. While the artisan may indeed have such skills, claims 42 and 43 explicitly encompass monoclonal antibody LYM 22. Note the language "A pharmaceutical composition comprising an isolated human monoclonal antibody... selected from the group consisting of mAb sHIgm22 (LYM 22)" in claim 42 and "A pharmaceutical composition comprising isolated mAb sHIgm22 (LYM 22) antibody" in claim 43.

The claims clearly encompass the actual monoclonal antibodies, not just any antibody comprising the recited sequences. Antibodies are defined not only by their small antigen-binding regions, but also by the remainder of their structure. The process of producing monoclonal antibodies is unpredictable; even when a small antigen is used multiple different monoclonal antibodies can be produced. See for example Kuby (1997. Immunology, Third Edition, pp. 131 – 134), which teaches the process by which monoclonals are produced. See also Alberts et al. (1994. Molecular Biology of the Cell, 3rd Edition, pp. 1216 – 1220). Alberts teaches the three-dimensional structure of antibodies is complex. Note particularly the large models on pp. 1219 – 1220 which indicate that the antibody molecules are comprised of hundreds of amino acids. The structure of a large protein such as an antibody is dependent not just on the antigen-binding region, but on the totality of the interactions of the hundreds of amino acid residues. Furthermore, Alberts teaches that the constant domains of the antibodies determine certain properties of the antibodies (see for example p. 1217, final paragraph).

The specification fails to disclose the complete sequence and structure of antibody sHIgM22, which is encompassed by claims 42 – 43. The art recognizes that specifying the sequence of the variable region alone is not sufficient to determine the entire structure of an antibody, and that making monoclonals is an unpredictable process. Monoclonal antibodies are so unique that a skilled artisan cannot simply construct one, the actual hybridoma which secretes the antibody must be present in order to make it. Thus deposit of said hybridoma is required for compliance with § 112, first paragraph. MPEP § 2404.02 recognizes that when undue experimentation would be required for an artisan to make a biological product, deposit can be required. The examiner has concluded that in order to make the actual antibodiy sHIgM22 (LYM 22), the hybridoma is required. However, for claims which do not recite this antibody, i.e. claims 73 and 91 – 93, the degree of experimentation required to make and use antibodies which comprise the disclosed sequences would not be undue.

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification lacks sufficient deposit information for the monoclonal antibody sHIgM22 (LYM 22). Because this monoclonal antibody is unknown, and therefore, publicly not

available and cannot be reproducibly isolated from nature without undue experimentation, a suitable deposit for patent purposes is required. Note that the antibody was isolated from a human patient (see Ciric et al. 2000, of record, and Warrington et al., 2001, of record, both of which teach isolation of the antibody from human samples) and it would not be expected to be reliably reproduced from any and all human patients.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification. In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

For the reasons above, it would not be possible for the skilled artisan to make the antibodies and fragments recited in claim 42, and the antibodies recited in claim 43. Therefore the rejection is maintained.

Conclusion

8. Claim 73 is allowed; claims 42 – 43 and 91 – 93 are rejected.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.
February 7, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER